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| 09/829,549      | 04/10/2001  | James T. English     | UMO 1521.1          | 8198             |

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ST LOUIS, MO 63102

EXAMINER

WESSENDORF, TERESA D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 05/07/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/829,549

Applicant(s)

ENGLISH ET AL.

Examiner

T. D. Wessendorf

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 10-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6-8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1639

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group I, claims 1-9, species type 8 vector and random oligonucleotide of GCAGNN(NNN)7 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that Group I and Group VI differ only in the last several steps and that the searched can be made without serious burden to the Office. Accordingly, it is argued that these Groups should be rejoined. This is not found persuasive because as applicants state the groups differ in the additional steps i.e., the steps of determining the effect of the peptides on a fungus. A prior art reference anticipating the method of identifying a peptide will not render obvious a method including the steps of determining the effect of the peptides (assay method) on the growth of a fungus. The search will entail an undue burden to the examiner since the literature and foreign searches are not coextensive with the U.S. Patent search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 10-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Art Unit: 1639

Applicant timely traversed the restriction (election) requirement in Paper No. 10.

***Specification***

The abstract of the disclosure is objected to because of the inclusion of phraseology often used in patent claims i.e., "comprising". Correction is required. See MPEP § 608.01(b).

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See e.g., page 23, line 5. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicants are requested to check for other codes in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: GCAGNN(NNN)7 is not in the disclosure. Cf. with page 12, line 6 of the disclosure.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors (grammatical, typographical and idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Art Unit: 1639

**Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description of the method for identifying a non-Ig peptide that with an affinity for the surface of any kind of fungi. Bishop Hurley (Pathopathology, page S7) discloses that the effect induced by a peptide was **species-specific**. No premature encystment was observed with two other *Phytophthora* species tested. The specification does not describe any other fungus that has been affected by a peptide from any random library or even with another single peptide. The description in the specification drawn to a random oligonucleotide that encodes the peptide of Seq. ID. 1 with fungal specificity binding does not

Art Unit: 1639

provide an adequate written description for the numerous undefined variables of claim 1. [Incorporating the limitation of claims 3 and 5 to claim 1 would obviate this rejection].

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). "Capable" in claim 1 connotes uncertainty i.e., whether the host has been positively transfected by the fusion vector.

B). Claim 8 method of "estimating" is indefinite as to how said estimation is made. It is suggested that applicants recite the numerical range of said binding affinity.

C). Claim 9 is indefinite as to whether the peptides contained in the library is of the same length of 6 residues or of varying lengths of from 6-15 residues.

Art Unit: 1639

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gyuris et al (US 6,420,110) or Massey (WO 99/51780).

Gyuris et al discloses at col. 4, lines 25-36 a method for generating a peptide with a selected antimicrobial activity against a fungus comprising: providing a recombinant host cell population which expresses a soluble peptide library comprising a variegated population of test peptides; culturing the host cells with a target microorganism under conditions wherein the peptide library is secreted and diffuses to the target microorganism; and selecting host cells expressing the test peptides that inhibit growth of the target microorganism. The target microorganism is a bacteria or a fungus. At col.1, line 59 up to col. 2, Gyuris discloses a method of identifying or

Art Unit: 1639

selecting a peptide with a selected biological activity, comprising the steps of: (i) providing a peptide display library comprising a variegated population of test peptides expressed on the surface of a population of display packages; (ii) in a display mode, isolating, from the peptide display library, a sub-population of display packages enriched for test peptides which have a desired binding specificity and/or affinity for a cell or a component thereof; (iii) in a secretion mode, simultaneously expressing the enriched test peptide sub-population under conditions wherein the test peptides are secreted and are free of the display packages; and (iv) assessing the ability of the secreted test peptides to regulate a biological process in a target cell. The peptide display library can be a phage display library, e.g., which utilizes phage particles M13. Gyuris discloses the random peptide libraries at col. 10, lines 11-40. The Bacteriophage vector type 8, cp VIII is described by Gyuris at col. 12, lines 1-60 and col. 14, line 64 u p to col. 15, line 30. It would have been obvious to one having ordinary skill in the art at the time the invention was made to pick or choose fungus as the microorganism as positively taught by Gyuris. One would have been led or motivated to chose fungus from the teaching of Gyuris, if this is the desired pathogen to be eradicated.



Art Unit: 1639

Massey basically discloses the same method as Gyuris.

Massey discloses a method of identifying a peptide from a random peptide library transfected into a vector and introduced into a host then reacting the displayed peptide with the target pathogen, fungus, inter alia. See page 3, line 28 up to page 8, line 31.

The claimed library of claim 1 is obvious using commercially available random peptide libraries or to modify using the known techniques.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

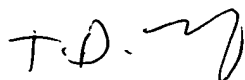
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/829,549

Page 9

Art Unit: 1639



T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw

May 1, 2003